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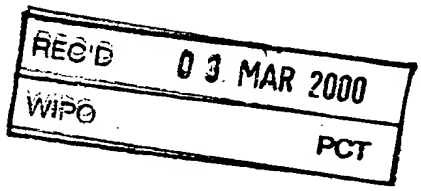

Keksinnön nimitys
Title of invention

"Device for restorative dentistry"
(Laite korjaavaa hammashoitoa varten)

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Device for restorative dentistry

This invention concerns a device for filling and reinforcing an internal tunnel in a tooth from which tooth approximal caries has been removed by means of a tunnel preparation and for preventing overhangs.

When human teeth are damaged through demineralisation process caused by bacterial acid attacks this occurs practically always on very specific tooth sites which have been colonized by cariogenic micro-organisms. Interproximal and occlusal tooth surfaces are the main colonization sites of aciduric and acidogenic mutans streptococci which are the main causative bacteria of human dental caries.

Matrix bands made of metal or cellulose acetate and interdental wedges made of limited adaptable wood or nonadaptable plastic have been traditionally used as aids to restore cavities prepared into caries affected teeth according to G.V. Black's principles. Today's modern primary cavity management considers these aids and principles as obsolete, since they are absolutely too invasive, destructive and even problem creating. The technology of tooth restoration has definitively changed from macro- to microconservative management of the decay. It is no more necessary to extend the cavities for prevention since cariostatic restorative materials, such as fluoride releasing glass ionomers, are available. Also extension for retention is not necessary since adhesive restorative materials, such as composite resins, glass ionomers and compomers, can be bonded to tooth hard substances, enamel and dentin.

With increasing concerns about microleakage and possibility of overfilling, as far macroconservative management of large cavities treated with conventional Class II composite resin restorations and inlays is concerned, there is a desire to cut down especially on gum related approximal and marginal perimeter of restorations. The shorter the margin of the cavity preparation, the less the poten-

tial for marginal breakdown, leakage and overfilling. Handling of composite resin and glass ionomer materials in conventional box like or round bevel shaped approximal cavity preparations is not easy, since these materials tend to "over flow" to overhangs below the gum line which then serve as niches for facultative anaerobic gram-negative flora to colonize. Several recent studies have shown that the type of oral microflora, which causes chronic periodontal infections, often accompanied with uneven vertical bone loss around the "affected" tooth, also spreads out during episodes of dental bacteremia to heart and other organs clogging arterias. This triggers severe health conditions, such as coronary heart diseases, strokes and is also associated with pre-term low birthweight infants (Mattila et al. 1989, Syrjänen 1990, DeStefano et al. 1993, Beck et al. 1996, Joshipura et al. 1996, Herzberg & Meyer 1996, Scannapieco & Mylotte 1996, Grossman et al. 1997, Dasanayake 1997, Curtis 1997). When gums become inflamed due to contact with a marginal foreign body (overfilled restoration) and nit growing bacterial plaque, gingival sulcus is lined by an ulcerated epithelium. Capillaries beneath such an epithelium bleed spontaneously even after passage of food or a toothbrush over the gingival margin and allow different bacterial species to enter and survive in the bloodstream. Alone stroke incidence in the U.S. is dramatically higher than once thought. Some 700.000 occur each year, 40% more than previously estimated (Time magazine's citation from Journal of the American Medical Association and Stroke, 1998). It seems clear that overhangs/overfillings of dental restorations, which maintain chronic periodontal inflammation breaching the mucosal lining are by all means to be avoided, then even normally harmless streptococci as commensals of the normal oral flora behave as thrombogenic agent after having encountered platelets in bloodstream (Herzberg 1996).

Further conserns in conventional approximal cavity management, in which the marginal ridge has been removed to get access to the carious lesion, is the fact that direct composite resin restorations do not warrant stable contact points. This is due to difficulty to manipulate sticky or flowable composite material to tight contacts to the adjacent teeth. Open approximal contacts lead to food impaction and retention. This forsters plaque accumulation and makes its removal difficult which within a short time causes inflammation of the dental papilla, i.e. the gum part between two adjacent teeth, and marginal gingiva. Consequent gingival pocket formation and bleeding due to food impaction contributes to dental bacteremia. Also proximal wear of composites generally questions the feasibility of their use in contact areas (Ziemiecki et al. 1992; Wendt et al. 1996).

The primary role of the restorative dentistry should be to restore what has been lost by the very disease itself and to preserve as much as possible of the remaining hard tissue, of intact enamel and dentin. As the initial carious lesion occurs underneath the contact point, underneath the marginal ridge, there is no need to destroy the contact point and the ridge to get access to carious lesion. Tooth's marginal ridge should by all means be preserved to ensure a stable approximal contact.

The understanding complex relationships had led to more accurate dental care. The need for operative treatment of approximal carious lesions depends on whether or not the surface is cavitated. The sensitivity of dental radiographs, i.e. the ability to correctly diagnose, for detecting interproximal caries was earlier reported to be 59.4% (Douglass et al. 1986). Cavity detection in approximal tooth surfaces by means of digital images, e.g. by using storage phosphor system, opens new possibilities to determine that very condition / "moment" when an early caries

lesion has penetrated into dentin and a primary restoration is indicated more accurately (Wenzel et al. 1991, Nielsen et al 1996, Svanaes et al. 1996). It is of importance to choose a restoration procedure that allows a simple and complete access to the lesion without destroying the tooth's own natural and stable contact point which practically is never affected by initial caries. The filling procedure itself should be chosen so that no new further problems, such as marginal breakdown, microleakage and/or overfilling are created, which would have health hazardous consequences.

Since widely used conventional tooth restoring procedures are unnecessarily radical, extensive and complex, simpler procedures have been sought. Microconservative "internal tunnel" preparation as described by Jinks 1963 as well by both Hunt and Kent independently 1984, presents a very sophisticated method to treat the carious proximal lesion without loosing the important natural contact point between two adjacent teeth. From the occlusal approach a small round bur is passed down starting through central main fissure until the dentinal "approximal" lesion which can be easily identified in the inside of the tooth as a dark brown/black stripe and/or by probe which sticks. As the dentin caries has been removed, the overlying porous enamel, through which the initial lesion has passed into dentin, can easily be identified as demineralized enamel and punched-out.

To ensure complete caries removal without weakening the marginal ridge unnecessarily, tunnel preparations are performed using extra fine instruments, preferably under an operating microscope similar to endodontic treatments. The operating microscope allows better visualization of the working field, ensuring that the caries process inside of the tooth is more readily inspected with bright illumination and magnification. The principles of microsurgery

in restorative dentistry are relatively new and allow the clinician to perform the treatment so that the strength of the prepared tooth remains 92% and more of the sound value (Hill & Halaseh 1988).

No doubt the ability of filling materials (also called cements, i.e. syntetic analogues for enamel and dentin) to support the marginal ridge with an underneath preparation increases as the diameter of the tunnel itself decreases. Tunnel cavities have been filled by introducing kneadable, low viscous or flowable restoration materials from the occlusal approach using conventional hand instrumental application of injection. To fill such a cavity of a small diameter through one opening, especially if the air escape is not optimally provided, is difficult, if not impossible. Indeed by conventional "orthograde" filling access air will be clogged in the cavity since the other end of the tunnel is closed by a matrix band. Air cushion hinders and impedes the complete filling of the tunnel. To gain maximal reinforcing and maximal strength of the restored tooth, it is of importance to fill the tunnel completely and bubble-free with an adhering material.

Glass ionomer cements, composite resins and their mixtures, also called compomers, are for the moment the materials of choice to restore tunnel cavities. It has been shown that a proper filling of a tunnel cavity with glass ionomer, the undermined marginal ridge can be considered reinforced and fracture susceptibility of the area is eliminated (Hill & Halaseh 1988). To prevent recurrent caries of the operated area, glass ionomer or other fluoride leaching or anti - mutans streptococci - agent containing/releasing materials are preferably to be used. It has been reported that composite resin materials containing Ag+ (silver) fillers or Apacider-fillers (Ag, Zn) or other antibacterial fillers hinder the growth of mutans streptococci (Yamamoto et al. 1996, Syafiuddin et al.

1997) and so reduce the danger of recurrent caries of the primarily treated area.

Whichever filling materials and devices are used, it is of utmost importance to have a proper control of the procedure. Two important characteristics which cause failures in conventional tunnel restorations when filled from occlusal approach are:

1) Incomplete filling. Since visual control and air escape are not provided. There is no way to ensure the tunnel is filled completely until the very end. Use of injection cannulas does not solve this problem, since they cannot be pushed through the entire tunnel system. Cannulas are also too thick, since they have to have a certain diameter to be able to pass the viscous filling material.

2) Overfilling. There is no visual control over concave tooth contours which may cause leakage under a conventional matrix band

The object of the present invention is to eliminate the above problems, which is achieved with a device according to the characterizing part of claim 1.

By means of this device an internal tunnel cavity can be filled and reinforced e.g. with an adhering synthetic filling material from approximal access, i.e. retrograde filling, while air escape from the tunnel cavity through an uncovered occlusal opening of said tunnel is guaranteed. The first flexible container means acts as a special interdental device and releases the flowable restoration or filling material into the tunnel cavity from the approximal access.

According to a prefered embodyment the device is further provided with a second flexible container device, attached

to the first flexible container device by means of an isthmus, which second container device is aimed to be used for sealing the approximal cavity perimeter, which may be very short, during a curing phase of the filling material, as soon as the filling of the entire tunnel cavity has been completed.

Below the device according to the present invention will be described in more detail, with reference to the drawing, showing a schematic side view of a prefered embodiment of the device.

The device comprises a cartridge or syringe 1 containing an adhering synthetic filling material, which may be self, dual, chemically or light curable. One end of the cartridge 1 is shaped to be adaptable to an applicator device, for instance a pistol like applicator device of Centrix Inc. The other end of the cartridge 1, is tapered and provided with an outlet opening 2 communicating with the cavity of an empty, elongated and flexible container means 3, preferably made of nylon. The end of the flexible container means 3 is preferably laser or heat bonded to the tapered end of the cartridge 1. The other end of the flexible container means 3 is closed. The closed end of the flexible container means 3 is provided with a tip, to facilitate said container means 3 to be threaded between teeth.

According to a prefered embodiment of the invention the closed end of said first flexible container means 3 is attached, preferably by means of an isthmus 4 or a seam to an end of a second closed and empty flexible container means 5, the opposite end of which is provided with a tip 6, which is aimed to facilitate the handling of the device, i.e. the thread of the both empty container means 3 and 5 between teeth.

If the filling material in the cartridge 1 is of a light curable type the cartridge 1 should be photblocked, preferably by using a see through orange plastics or a 100% photoblock material for manufacturing the cartridge 1.

The first flexible container means 3 is preferably substantially cylindrical having a diameter of about 2 mm and a length of about 20 mm. The second flexible container means 5 is preferably slightly conical widening against the tip 6. The diameter in the end close to the first flexible container means 3 is about 2 mm and the diameter in the end provided with the tip 6 is about 3,2 mm and the length of the second flexible container means is 60 to 120 mm. The material of the first and the second flexible container means 3, 5 may be a transparent nylon or an analogue transparent material. However, if the filling material in the cartridge 1 is of a light curable type, the first flexible container 3 could advantageously also be photoblocked, for instance by manufacturing it of a see through orange nylon or an analogue materal. The isthmus 4 and the tip 6 are preferably laser bonded.

Before use both flexible container means 3 and 5 are in a flat condition, preferably vacuumized.

The use of a device according to the invention is described below step by step.

- A lesion and its relation to anatomic structures of a tooth is located by means of a preoperative radiological digital image.

- The affected tooth is anesthetized.

- After the placement of a rubber dum interdental accessories such as Wedjets dam cord as color indicator, fiber

optic illumination and a metal matrix piece are used to guide and protect during the preparation procedure.

- An occlusal access preparation is made into center fissure of the tooth with a high speed, water-cooled bur or by means of air-abrasive technology, i.e. kinetic cavity preparation.

- In the fiber optic illumination bright yellow or red interdental cord (Wedjets) glimmer through the enamel guiding the operator to remove approximal caries but saving as much as possible of the intact enamel. Aim is to pass the bur underneath the contact point between the damaged tooth and an adjacent tooth through the enamel, just there where caries penetrated into the tooth. The interdental matrix band will protect the adjacent tooth.

- Caries removal is verified e.g. by caries detector, using hand-instrument probing, suitable rotary instruments and/or carisolv system in direct vision preferably under an operating microscope with bright illumination and magnification. However, microscope is only an option and is not necessarily needed.

- Enamel margins of approximal and occlusal openings are finished by suitable diamond or tungsten carbide burs.

- Wedjet dam cord and matrix band are removed.

- Smear layer is removed with air-water spray and then the tooth is gently dried by stream of warm air.

- Tunnel-cavity is "primed" to receive filling material following the instructions of the manufacturer (primer / conditioner / etch gel / bonding resin -system).

- The device according to the invention, with the flexible container means 3 and 5 in a flat and empty condition is placed interdentally by pressing the first flexible container means 3, analogue to the use of a dental floss through the contact point from occlusal access or by threading the both flexible container means 5 and 3 by the aid of the tip 6 from palatal/lingual respectively buccal access under the contact point. The filling material in the cartridge 1 is then pressed by an applicator device into the first flexible container means 3, which fills up and adapts itself tightly on the approximal surfaces below the contact point of the two adjacent teeth. Now the flexible container means 3 covers tightly the approximal opening of the prepared tunnel cavity.

- The operator punches from the occlusal access through the prepared tunnel a small hole into the first flexible container means 3 with a suitable needle (analogue to an endoinstrument). By maintaining a constant pressure inside the first flexible container means 3 by pressing the applicator device, the low viscous filling material will flow slowly from the first flexible container 3 into the tunnel through the approximal access.

- The tunnel cavity is then slowly filled by the filling material under bear eye control. As soon the material has reached the margins of the occlusal cavity the pressure is released. The device is then pulled laterally until the - first flexible container means 3 is pulled out from the interdental space and the second flexible container means 5 takes its place. The end portion of said second flexible container means 5, provided with the tip 6, is then cut away along a cut line 7 and the thus opened end of this second container means 5 is connected to a dentist's air blower, a pressurized water supply or a syringe containing a special fluid, by means of which said second container means 5 is pressurized and maintained pressurized, so that

said container means 5 seals tightly the approximal opening of the filled tunnel cavity. While said second container means 5 is maintained pressurized the filling material is preferably polymerized by using a three sited (partly trans enamel) light curing technique. The curing time per site is 60 seconds or shorter. By using argon laser a curing time of 7.5 seconds may be sufficient.

- The second flexible container device is then depressurized and removed by further pulling the whole device laterally away.

- The occlusal surface of the tooth is then adjusted and polished. A fluoride solution, varnish, gel etc. is applied occlusally and interdentally. Due to the device according to the invention the approximal surface needs no checking for overhangs and marginal imperfections.

If a syringe, containing a special fluid, is used to pressurize the second container means 5, some further advantages are achieved. Said special fluid can for instance contain antibacterial phytochemicals (naturally occuring chemicals) such as immunoglobulins (specific antibodies), lysozyme, lactoferrin and complement components. All these have been found among the host molecules in the conditioning film of proteins and glycoproteins which are rapidly adsorbed from saliva to the non-shedding oral surfaces (Östravik & Kraus 1973, Pruitt & Adamson 1977, Rølla et al. 1983, Al-Hasimi & Levine 1989, Jensen et al. 1992). After the polymerization of the filling material has been completed and the biting surface has been adjusted into occlusion, engineered molecule structures, e.g. such as those converted into human antibodies, can be released over the freshly treated surface by puncturing the second container means 5 interdentally with a needle. This procedure aims to determine a defensive architecture of a specific dental biofilm (the acquired enemal pellicle) to

hinder a recolonization of the treated surface by cariogenic microflora or other pathogens (James & Bell 1987, Ma & Lehner 1990, Winter & Harris 1993, Ma & Hein 1995, Loimaranta et al 1997). Alternatively the special fluid can contain antiplaque or antimicrobial agents as used widely in toothpastes and mouthwashes such as fluorides, metal salts (stannous,zinc), bisbiguanides (chlorhexidin), phenols (Triclosan), enzymes (glucan hydrolases), quaternary ammonium compounds (cetylpyridinium chloride) and Delmopinol alone or in combinations (Scheie 1989, Marsh 1993).

Claims:

1. A device for filling and reinforcing an internal tunnel in a tooth from which tooth approximal caries has been removed by means of a tunnel preparation and for preventing overhangs, characterized by a cartridge or syringe (1) containing a filling material, having one end adaptable to an applicator device and another tapered end provided with an outlet opening (2) connected to one end of an empty, elongated and flexible container means (3), the opposite end of which being closed.

2. A device according to claim 1, characterized in that the closed end of the first flexible container means (3) is attached, preferably by means of an isthmus (4), to an end of a second closed and empty, flexible container means (5), the opposite end of which being provided with a tip (6).

3. A device according to claim 1, characterized in that the cartridge (1) is 100% photoblocked, or preferably made by a see through orange photoblocked plastics.

4. A device according to claim 2, characterized in that the first and the second flexible container means (3, 5) are made of transparent nylon or analogue transparent material.

5. A device according to claim 1 or 2, characterized in that the first flexible container means (3) is made of photoblocking nylon, preferably of a see through orange nylon or analogue material.

6. A device according to any of the claims 3 to 5, characterized in that the first flexible container means (3) is laser, heat or chemically bonded to the outlet end of the cartridge (1).

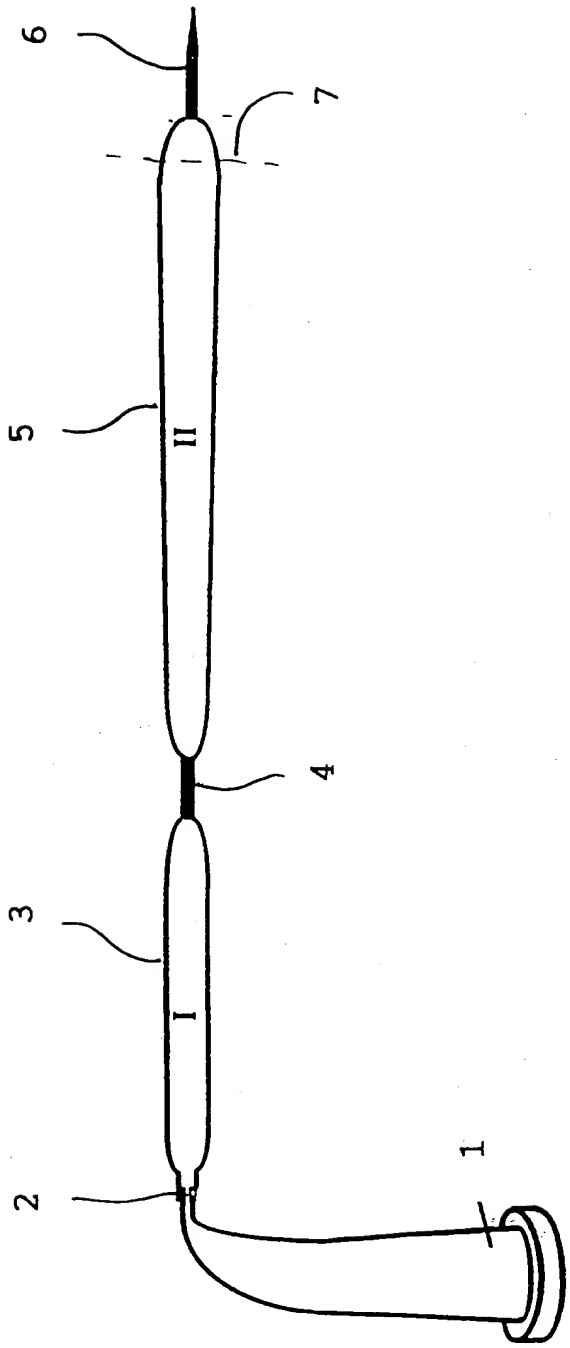
7. A device according to any of the claims 3 to 6, characterized in that the isthmus (4) and the tip (6) are heat or laser bonded.

8. A device according to claim 2, characterized in that the first flexible container means (3) is substantially cylindrical and the second flexible container means (5) is cylindrical or slighty conical, widening against the tip (6).

9. A device according to any of the preceeding claims, characterized in that both flexible container means (3, 5) are in a vacuumized thin and flat condition before use.

(57): Abstract:

This invention refers to a device for filling and reinforcing an internal tunnel in a tooth from which tooth approximal caries has been removed by means of a tunnel preparation and for preventing overhangs. The device is characterized by a cartridge or syringe (1) containing a filling material, having one end adaptable to an applicator device and another tapered end provided with an outlet opening (2) connected to one end of an empty, elongated and flexible container means (3), the opposite end of which being closed.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